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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,477	06/22/2001	Arnold J. Reuser	24512-X	6846

20529 7590 08/14/2003

NATH & ASSOCIATES
1030 15th STREET
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WASHINGTON, DC 20005

EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

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DATE MAILED: 08/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/886,477

Applicant(s)

REUSER ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,40 and 41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26,40 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>16</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed June 30, 2003, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Note that claims 38 and 38 were originally presented at the time of filing, and were cancelled in the amendment filed November 15, 2001.

Newly presented misnumbered claims 38 and 39 have been renumbered 40 and 41.

Claims 1-25 and 27-37 have been cancelled.

Claims 40 and 41 have been added.

Claims 26, 40 and 41 are pending and are examined on the merits.

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Priority

As discussed on pages 4-6 of the office action of May 1, 2003, the earliest priority date applicant can be granted is January 29, 2001, the filing date of Application Serial No. 09/770,253, the C-I-P parent of this case. It is noted that applicant has filed a request for corrected filing receipt wherein priority is claimed to application serial number 08/700,760, through its reissue application, serial number 10/046,180. However, as stated in the response to the request for corrected filing receipt, a claim for priority cannot be based on a later filed application. See 35 U.S.C. § 120.

Claim Rejections - 35 USC § 102

Claims 26, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Corven et al (WO 99/51724).

Van Corven describes the intravenous administration of up to 10 mg purified human acid α -glucosidase to patients suffering from lysosomal enzyme deficiency disease. See, e.g., page 32, lines 4-19. Note specifically that the reference inherently meets the claimed limitation requiring liver, heart and muscle cell uptake because the reference describes administering the same ingredient to the same patient at the same dosage. Note

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further that the reference also discloses the claimed purity limitation, stating on page 21, lines 13-17 that the most preferred pharmaceutical compositions comprise essentially homogeneous enzyme. A holding of anticipation is clearly required.

Claims 26, 40 and 41 are rejected under 35 U.S.C. 102(a) as being anticipated by Van Bree et al (WO 00/34451).

Van Bree describes the intravenous administration of up to 40 mg purified human acid α -glucosidase to patients suffering from Pompe's disease, and that the enzyme will be taken up by liver, heart and muscle cells. See, e.g., page 18, line 7, through page 19, line 20. Note further that the reference also discloses the claimed purity limitation, stating on page 5, lines 22-25, that the most preferred pharmaceutical compositions comprise essentially homogeneous enzyme. See also page 17, lines 23-28, disclosing greater than 95% pure enzyme from transgenic rabbits. A holding of anticipation is clearly required.

Claims 26, 40 and 41 are rejected under 35 U.S.C. 102(a) and 102(e) (2) and 102(f) as being anticipated by Reuser et al (U.S. Pat. 6,118,045).

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Reuser discloses the administration of human acid α -glucosidase to a human patient suffering from Pompe's disease, wherein the enzyme is administered intravenously, and wherein the enzyme is purified to homogeneity. Note specifically that the reference inherently meets the claimed limitation requiring liver, heart and muscle cell uptake because the reference describes administering the same ingredient to the same patient at the same dosage. See claims 18-20, at column 18, lines 38-47. Note further that therapeutic dosages are defined therein as generally from about 0.1 to 10 mg purified enzyme per kilogram of body weight. See column 12 at lines 20-23. A holding of anticipation is clearly required.

Response to Arguments

All of applicant's argument regarding the above grounds of rejection has been fully considered but is not persuasive of error. Applicant argues that none of the prior art cited above can be considered prior art over the cited claims in view of the amended claim to priority. However, as discussed above and stated in the response to the request for corrected filing receipt, a claim for priority cannot be based on a later filed application. See 35 U.S.C. § 120. The prior art rejections must therefore be maintained.

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No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner

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can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Francisco C Prats
Primary Examiner
Art Unit 1651

FCP
August 11, 2003